

March 15, 1999

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
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**RE: Docket No. 99D-0254  
Draft Guidance for Industry on Product Name Placement,  
Size, and Prominence in Advertising and Promotional Labeling**

Dear Dr. Hubbard:

We are hereby commenting on the subject Docket listed on page 12341 of the Federal Register Vol. 64, No. 48, dated March 12, 1999. "Draft Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling".

In the draft guidance, the fourth paragraph in the Introduction states, "For biological products, the regulations regarding position and prominence of the trade name and proper name of products, as described in 21 CFR 610.62, apply only to the container and package labels."

We wish to point out that section 21 CFR 610.62 was deemed not applicable for products approved under a Biologics License Application per the FDA Final Rule, "Elimination of Establishment License Application for Specified Biotechnology and Specified Synthetic Biological Products," published in the Federal Register volume 61, No. 94, dated May 14, 1996. At that time, it became acceptable to feature on the product labels the trade (or proprietary) name above or before the proper (or established) name for specified biologics. The newly issued Draft Guidance for Industry does not mention this exception, and appears not to recognize that the regulation was revoked for the majority of biologic products.

Please clarify this situation in the Final Guidance when it is issued. If we are incorrect in our understanding, please explain the status of the Regulation under 21 CFR 610.62, by calling Lisa Suttner, Manager, Regulatory Affairs at (609) 987-5877.

Sincerely,

NOVO NORDISK PHARMACEUTICALS, INC.

  
Barry Reit, PhD

Vice President, Regulatory Affairs

99D-0254

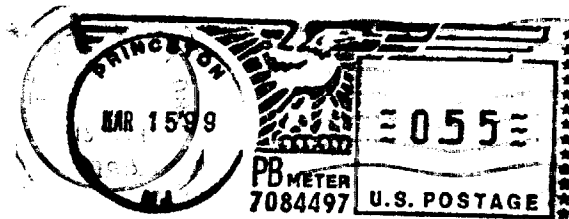
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